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Henry Ford Hospital
2799 West Grand Boulevard
Detroit, Michigan 48202-2689
(313) 876-2241 Office
(313) 876-7139 Fax

December 1, 1999

Midwest Neuro-Oncology Center
Cerebrovascular Surgery
Skull Base Surgery
Epilepsy Surgery
Pain & Movement Disorders
Stereotactic Surgery
Surgery for Spinal Disorders
Brain & Spinal Cord Injury
Pediatric Neurosurgery

The Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, Maryland 20852

RE: Docket #97N-4084S

To Whom It May Concern:

I am writing to comment on an article I 'came across in the Federal Register, issue September 30, 1999. I am a neurosurgeon in a large, multispecialty practice at Henry Ford Hospital in Detroit. We do an extensive amount of cervical, thoracic, and lumbar spine surgery. We heavily rely on allograft bone for fusion. We obtain the allograft from bone banks, and my understanding of the article in the Federal Register suggested that the requirements which the FDA might impose upon the bone banks would be prohibitive. This being the case, we would expect to have a diminished supply of allograft. This would severely affect our ability to do spinal fusion cases. Certainly, we can use the patient's own bone for this process, but as you may or may not know, this process carries its own morbidity, not the least of which is pain at the site of the graft.

I would strongly urge you to reconsider any restrictions on the availability of allograft to those of us in clinical practice. Not only will it affect our ability to manage certain types of spinal fusions, but it will have a general effect across the board on spinal surgery if the availability diminishes. I would greatly appreciate any update on this issue. I am also currently the president of the Michigan Association of Neurologic



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Surgeons and would assure you that across the board the neurosurgeons in the state would echo my concerns.

Sincerely,



Jack P. Rock, M.D.
Department of Neurosurgery

cc: Dr. Mark Rosenblum, Neurosurgery

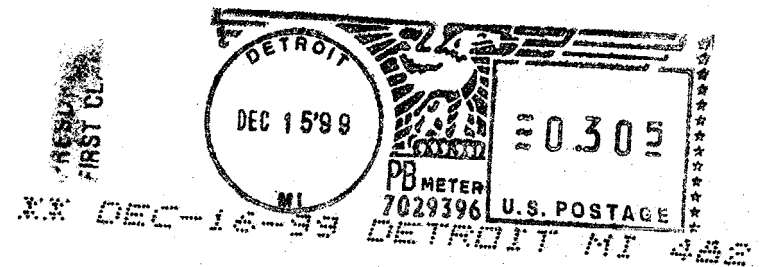
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HENRY FORD HOSPITAL

Department of Neurosurgery

2799 West Grand Boulevard
Detroit, Michigan 48202



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